Exhibit 1

Smart Insurance Company

v.

Benecard Services, Inc.

Expert Witness Report

Signed: 

Erin Costell

Navigant Consulting, Inc.

April 18, 2016

Table of Contents

Attachments & Appendices

I. INTRODUCTION

1. My name is Erin Costell. I am a Director with Navigant in the Healthcare and Life Sciences Disputes, Compliance and Investigations practice, and I lead the Pharmacy Compliance Service Sector. I have over 16 years of experience in healthcare operations and consulting. I have specialized in Medicare Part D operations and compliance since its inception. I have substantive experience, previous to Navigant, as a vendor and first tier, downstream and related entity ("FDR") within the Medicare Part D program, having owned, developed and operated a Healthcare IT company responsible for Medicare Part D front end processing. Due to my prior experience and my role as a consultant, I am familiar with Medicare Part D program requirements for plan sponsors, program requirements for FDRs and the working relationship that exists between FDRs and plan sponsors in the Medicare program.

2. Navigant is an international consulting firm with offices located throughout the world. Our firm is comprised of more than 2,500 professionals including: economists, certified public accountants, econometricians, information technology specialists, certified business appraisers, chartered financial analysts, certified fraud examiners, professional engineers, and industry experts. Navigant's work in this matter was performed by me or by those under my supervision, who were compensated at standard hourly rates ranging from $225 to $500.

Navigant is being compensated at a rate of $600 per hour for my work on this matter. The compensation to Navigant for my services as well as for those under my supervision is not dependent on the outcome of this matter.

3. A copy of my curriculum vitae is attached to this report as **Attachment 1**.

4. Navigant has been retained by Smart Insurance Company, Inc. ("Smart") in the above-captioned litigation which Smart filed against Defendant Benecard Services, Inc. ("Benecard") to provide expert testimony regarding Benecard's performance as a contracted Medicare Part D Pharmacy Benefit Manager ("PBM") and First Tier, Downstream and Related Entity ("FDR")[1] and Smart's oversight of Benecard.

II. SUMMARY OF SCOPE & OPINIONS

5. I have been asked to review the data and documentation available in this matter regarding Benecard's alleged failures as a PBM/FDR. I was retained to perform the following analyses:

a. ***Evaluate whether Benecard provided real-time enrollment and claims system access that is consistent with industry standards and sufficient for Smart to perform administrative and oversight tasks under its agreement with CMS.***

[1] Smart v. Benecard: Complaint, filed June 8, 2015.

b. ***Evaluate whether Smart performed oversight of Benecard as a first tier entity consistent with CMS' guidelines and industry norms.***

c. ***Evaluate whether Benecard operated in a manner consistent with Medicare Part D program requirements.***

6. The following opinions and analyses are based upon the information provided to date and my experience with the subject matter:

a. ***Real-time enrollment and claims system access was necessary for Smart to perform its duties under its agreement with CMS; but Benecard did not provide access to enrollment and claims systems and data that is typical within the market or necessary for Smart to perform administrative and oversight tasks.***

b. ***Smart conducted oversight of Benecard consistent with CMS' guidelines and industry norms. The effectiveness of certain oversight activities was hindered in part because of Smart's lack of complete and reliable real-time access to Benecard's enrollment and claims systems and data.***

c. ***Benecard did not operate in a manner consistent with certain Medicare Part D program requirements.***

7. I have relied on certain documents in forming the conclusions contained in this report. A list of these documents is attached to my report in **Attachment 2**. My analyses have been performed based on the information now available to me. As additional information

becomes available, I may evaluate and consider that information. As a result, I reserve the right to modify or supplement my opinions and conclusions.

III. BACKGROUND

8. In order to help provide contextual background pertaining to the analyses I have performed, the following section provides information on the relationship between Smart and Benecard, as well as the general structure of the Medicare Part D program and the role of FDRs. For more detailed information surrounding the Medicare Part D program and the role of FDRs, please refer to Appendix A.

9. The Voluntary Prescription Drug Benefit Program ("Part D"), established through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), is an optional prescription drug benefit for individuals entitled to Medicare benefits under Medicare Part A or Part B.[2] Medicare Part D "plan sponsors" are nongovernmental entities that execute a contract with CMS, permitting them to offer Medicare Part D prescription drug benefits pursuant to federal laws and CMS regulations.[3] Smart applied to become a Medicare Part D plan sponsor in 2012 for the 2013 plan year.[4]

[2] National Health Policy Forum "The Medicare Drug Benefit (Part D)", January 4, 2016.
[3] 42 C.F.R. 423.4
[4] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 24-26).

10. A Part D plan sponsor may meet program requirements by delegating the performance of certain required functions to entities with which it contracts directly[5], referred to in the Part D regulations (42 CFR §423.501) as "first tier entities." PBMs, which provide fundamental services such as processing prescription drug claims for plan sponsors and negotiating with pharmaceutical companies and pharmacies, essentially acting as an intermediary between the payers, suppliers and providers within the pharmacy benefit delivery continuum,[6] are examples of "first tier entities".[7] Benecard is a PBM contracted by Smart to provide PBM services for Smart's Medicare Part D plans and function as a "first tier entity" under Smart's contract with CMS.[8]

11. As part of the application process to become a Medicare Part D plan sponsor, CMS requires the applicant (Smart) to list all first tier, downstream or related entities ("FDRs") that the applicant has contracted with to perform certain required functions of the Part D plan.[9] Medicare Part D plan sponsors' applications are due in February of the year prior to the

[5] Medicare Part D Prescription Drug Benefit Manual (Medicare Part D PDBM) Chapter 9, Section 40.
[6] Thomas Gryta "What is a 'Pharmacy Benefit Manager?'," *The Wall Street Journal*, July 21, 2011.
[7] Medicare Part D PDBM Chapter 9, Section 40.
[8] Pharmacy Benefit Management Agreement (PBMA) between Smart and Benecard (SMT00311316 - SMT00311369)
[9] Solicitation for Applications for Medicare Prescription Drug Plan 2017 Contracts Section 3, (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2017-Part-D-Application_FINAL.pdf).

effective year of the program.[10] This means that for Smart's plan to go into effect on January 1, 2013, Smart needed to determine by the application deadline in February 2012: (1) what services would be performed through FDR relationships, and (2) which vendors Smart would be using to perform those functions.

12. In March 2012, Smart executed a Pharmacy Benefits Management Agreement ("PBMA") with Benecard to function as the PBM for Smart's Medicare Part D plans in 2013.[11] As stated in the PBMA, Benecard "provides, manages and administers prescription drug programs, including maintaining a nationwide network of pharmacies, administering Claims, as hereafter defined, generating prescription drug management and utilization reports, managing formulary and rebate services, member enrollment services, administration services and other pharmacy management services (collectively, "PBM Services").[12]"

13. In addition, the PBMA states that "Benecard shall provide Company's designated individuals, as provided in Section 2.8, with online, real-time access to Benecard's prescription drug claims database regarding Beneficiaries."[13]

14. In plan year 2013, Smart had delegated a number of functions to Benecard for the administration of its Medicare Part D program, including but not limited to: handling all

[10] Health Plan Management System "Release of Notice of Intent to Apply for Contract Year 2013 Medicare Advantage (Part C) and Prescription Drug Benefit (Part D) Contracts, and Related CY 2013 Application Deadlines," October 21, 2011.
[11] PBMA (SMT00311316 SMT00311369)
[12] PBMA Recitals, (SMT00311317)
[13] PBMA, Section 2.11 (SMT00311325)

matters associated with member enrollment, managing the Plan formulary and adjudicating member claims for coverage at the point of sale, administering the coverage determination, appeal, and grievance process, providing Smart with online real-time access to Benecard's drug claims database and systems, running the call center and answering member questions, and complying with Federal law and CMS requirements.[14]

15. The PBMA states that Benecard "shall maintain a quality improvement and management programs in compliance with all applicable laws and CMS requirements and shall cooperate and coordinate with Company's programs, including, without limitation, providing information on quality matters and assisting in the implementation of corrective action plans."[15] In the case of an audit, "Benecard agrees to reasonably cooperate with Company in conducting its audit, including, without limitation, providing Claims information to Company and the designated representative in Benecard's standard electronic format without additional charge."[16]

16. Because Benecard's role as Smart's PBM included many operational responsibilities, in order for Smart to fulfill its duties under its contract with CMS[17], it was

[14]Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 19).
[15] PBMA, Section 2.9 (SMT00311324)
[16] PBMA, Section 2.13 (SMT00311325)
[17] 42CFR 423.505(i)

imperative for Benecard to be accountable for its operational performance and to be transparent with Smart with respect to their data and systems[18].

17. Smart, as the plan sponsor, maintained accountability to CMS for the overall performance of the Plan regardless of whether services were performed itself or by a contracted FDR.[19] Therefore, Smart put several mechanisms into place in order to ensure that Benecard was meeting CMS' compliance standards. These include but are not limited to the following, which are discussed in more detail in my report: 1) a detailed PBM agreement with service level addendum; 2) use of Corrective Action Plans (CAPs) when an issue had been identified; 3) required real-time system access and management reporting; and 4) monitoring and auditing rights.

18. Smart uncovered a number of problems with Benecard's performance after the Plans were launched on January 1, 2013, including:

a. Its failure to properly handle and process a number of beneficiary enrollment requests;

b. Its failure to provide required information to beneficiaries in a timely manner;

[18] Medicare Part D PDBM Chapter 9, Section 30.

c. Its failure to provide a toll-free claims service to answer general program questions and specific inquiries from beneficiaries, providers and pharmacies;

d. Its failure to provide proper notice to Smart of certain compliance issues; and

e. Its improper rejection of claims at the point-of-sale.[20]

19. CMS issued a compliance notice and remediation request for inappropriately rejected Part D claims just weeks into the plan year in January 2013.[21]

20. CMS notified Smart on February 14, 2013 that it had been selected for a program audit covering the areas of Part D Formulary Administration and Part D Coverage Determinations, Appeals and Grievances[22]. CMS conducted an audit from March 13 – 15, 2013[23]. This audit resulted in 8 Immediate Corrective Action Requests (ICARs) related to Benecard's designated activities[24], and on April 23, 2013 CMS sanctioned Smart; suspending all enrollment and marketing activities.[25]

21. Despite opportunities to correct its deficiencies, Benecard could not remediate its operations in order to operate in a manner consistent with Medicare Part D requirements. CMS

[20] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 33).
[21] SMT00121502 - SMT00121503
[22] SMT00149162 – SMT00149164
[23] SMT00335619 - SMT00335621
[24] Ibid.
[25] SMT00002983 - SMT00002993

enumerated the ongoing issues in an email dated June 13, 2013.[26] The plan's continued poor performance and its inability to completely resolve administration issues led to CMS warning Smart to either sell the plan or face contract termination. Smart opted to sell the plan.[27]

IV. BASIS FOR OPINIONS

22. As discussed above, I was asked to perform the following review regarding the allegations in this matter:

a. ***Evaluate whether Benecard provided real-time enrollment and claims system access that is consistent with industry standards and sufficient for Smart to perform administrative and oversight tasks under its agreement with CMS.***

b. ***Evaluate whether Smart performed oversight of Benecard as a first tier entity consistent with CMS' guidelines and industry norms.***

c. ***Evaluate whether Benecard operated in a manner consistent with Medicare Part D program requirements.***

My opinions on each of the three topics listed above can be found below:

[26] SMT00175004; SMT00175005 - SMT00175008

[27] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 73-74).

23. ***Opinion A. Real-time enrollment and claims system access was necessary for Smart to perform its duties under its agreement with CMS; but Benecard did not provide access to enrollment and claims systems and data that is typical within the market or necessary for Smart to perform administrative and oversight tasks.***

24. In the pharmacy benefit industry, "real-time access" generally means access to the PBM's live claims system. Real-time claims system access is a tool that can provide the plan sponsor with access to the PBM's system to support benefit administration and plan sponsor oversight activities[28]. It is particularly important to have real-time access prior to the beginning of the plan year so that plan sponsors can test claims and ensure the Part D benefit would be administered properly; as is recommended by CMS in the Best Practices and Common Findings Memo #2 from 2012 Program Audits which states, "Perform comprehensive testing of formulary file and system edits prior to going "live" in the adjudication system (e.g., compare the CMS approved formulary file to the adjudication file to ensure all drugs, tier information, and utilization management edits are consistent)."[29]

25. It is an industry norm for PBMs to provide system access so that the plan sponsor can assess compliance with Medicare Part D program requirements. Furthermore, the PBMA states "Benecard shall provide Company's designated individuals, as provided

[28] Lucia Giudice, Director and Tom Longar, Sr. Associate (PwC Health Industries – Payer), HCCA Part D Compliance Conference, PBM Delegation and Oversight, December 11, 2007.
[29] HPMS "CMS in the Best Practices and Common Findings Memo #2 from 2012 Program Audits," July 30, 2013.

in Section 2.8, with online, real-time access to Benecard's prescription drug Claims data base regarding Beneficiaries."[30]

26. CMS also requires plan sponsors to be able to access its PBM's system in real-time during CMS audits. Attachment X of the Medicare Advantage & Prescription Drug Program Audit Process Overview states, "[CMS] will review sample cases live in the SO's [sponsor organization's] system and determine findings in real-time (although some determinations may be pended due to additional data requests)."[31]

27. Benecard did not provide access to its claims and enrollment data and systems in a manner sufficient to allow Smart to provide the oversight CMS requires. Benecard offered Smart three means of accessing their data; however, none of these means provided Smart with online, real-time access. First, in September 2012, Benecard offered to provide access to its system in the near future using OLE, a proprietary technology developed by Microsoft.[32] The OLE functioned as a user interface into Benecard's live enrollment and claims system, but Benecard limited the data elements that were visible to the user. The data available to Smart's users of the OLE system did not include many needed Part D specific data elements.[33,34] In October of 2012, Smart communicated to Benecard that the OLE system was not sufficient to

[30] PBMA, Section 2.11 (SMT00311325)
[31] Attachment X of the Medicare Advantage (MA) and Prescription Drug Plan (PDP) Audit Process Overview.
[32] SMT00020903
[33] Ibid.
[34] SMT00004705

meet its needs based on the data available through the user interface.[35] At that time, Smart provided a list of additional fields that would need to be visible in OLE in order for it to meet Smart's needs.[36] As of February 21, 2013, four months after the start of open enrollment and almost two months after the start of the benefit year, none of the additional fields had been added to OLE.[37]

28. Second, because of the data deficiencies in OLE identified in October 2012, Smart started using a workaround to perform its oversight testing; a process I'll refer to in my report as the "buddy system."[38] The buddy system was a means to allow Smart some visibility into Benecard's enrollment and claims system. With the buddy system, Smart and Benecard employees participated in a webinar during which the Benecard employee would display its screen showing parts of the Benecard enrollment and claims system.[39] Smart would direct Benecard as to what member to look up and what information Smart needed to review, in order for Smart to view Benecard's system and assess compliance with whatever operations Smart was reviewing.[40]

29. The buddy system did not qualify as Benecard providing Smart meaningful on-line, real-time system access to the enrollment and claims systems because Smart did not have

[35] SMT00020903
[36] SMT00024631, SMT00020903- SMT00020904
[37] SMT00020903
[38] SMT00866731; Deposition of Tammy Cappadonna 118: 17 – 119:5
[39] Deposition of Cheryl Williams 70: 3 – 71: 18
[40] Ibid.

access to Benecard's system during the buddy system sessions. It was a Benecard staff member's system access that Smart was viewing via a webinar during the buddy system sessions. The buddy system's effectiveness relied on, in part, the Benecard employee navigating the system during the review. Reviews conducted using the buddy system were limited to the information and system screens the Benecard employee was willing to show[41]. Also, the buddy system relied upon the availability of a Benecard employee in order for Smart to perform its quality assurance review.[42] Benecard could not always accommodate Smart's desired frequency or duration of requested webinars, which limited the oversight Smart could perform.[43]

30. Third, Benecard offered to Smart another workaround to the deficiencies of data availability in OLE by offering Smart access to its business intelligence software called Cognos.[44] The Cognos tool offered by Benecard did not provide "real-time access" because Cognos was a reporting tool.[45] Smart staff was not granted access to Cognos until January 2013.[46] Through its use of Cognos in January and February, Smart identified inconsistencies in the data available through Cognos and the source data from CMS, Wipro, and even reports

[41] Deposition of Danielle Panich 142:16-24
[42] Deposition of Danielle Panich 135:19- 136:16
[43] Deposition of Tammy Cappadonna 119: 9 - 22
[44] SMT00020903 - SMT00020904
[45] SMT00020419; SMT00026486
[46] SMT00020903

generated by Benecard.[47] As of January 2013, Smart still had no visibility into Benecard's operations in a manner that allowed for timely review and that could reliably gauge performance.

31. Smart continued to push for real-time access to Benecard's enrollment and claims systems. On January 15, 2013, Smart's Chief Operating Officer sent the President of Benecard an email offering to execute a confidentiality or non-disclosure agreement in order to be granted full access to Benecard's enrollment and claims system.[48] In February 2012, Smart received notification from CMS that it had been selected for an audit.[49] CMS audit procedures include the review of sample claims in real-time through a sponsoring organization's enrollment or claim system.[50] Meaningful real-time access to Benecard's enrollment and claims system was finally granted after the execution of the System Access agreement on March 5, 2013.[51]

32. At the point real-time access was provided, it was too late to have an impact as Smart had already been targeted by CMS for an audit based on past performance issues.

33. ***Opinion B: Smart conducted oversight of Benecard consistent with CMS' guidelines and industry norms. The effectiveness of certain oversight activities was hindered***

[47] SMT00020903 - SMT00020904
[48] SMT00006798
[49] SMT00149162
[50] Attachment X of the MA and PDP Audit Process Overview.
[51] SMT00312332 - SMT00312336

in part because of Smart's lack of complete and reliable real-time access to Benecard's enrollment and claims systems and data.

34. Smart structured its oversight of Benecard in a manner consistent with the oversight concepts discussed in Chapter 9, Section 50 of the Medicare Prescription Drug Benefit Manual. Chapter 9 of the Medicare Prescription Drug Benefit Manual, titled Compliance Program Guidelines, was designed to assist sponsors in establishing and maintaining an effective compliance program.[52]

35. Based on my experience, I would expect to see the below listed oversight activities performed by the Part D plan sponsor prior to the plan's effective date of January 1, 2013:

a. Establish a service level addendum listing performance requirements and penalties;

b. Review the FDR's policies and procedures;

c. Review the program using CMS's Readiness Checklist;

d. Conduct operational and compliance testing;

e. Employ effective lines of communication.

[52] Medicare Part D PDBM Chapter 9, Section 10.

36. It is my opinion that Smart performed all of the above listed activities. I have formed my opinion on the adequacy of Smart's oversight activities based on the facts discussed below.

37. ***Establishment of a service level addendum listing performance requirements and penalties:*** Service Level Addendums ("SLAs") are commonly included in vendor service agreements in order to clearly define performance requirements and penalties for failure to meet those requirements[53]. SLAs constitute an important part of a plan sponsor's oversight function because they formalize the sponsor's expectations of the vendor and establish a level by which to gauge a vendor's performance[54]. Performance outside of agreed-to terms would result in financial penalties and could be used as cause for termination of the agreement.[55] Thus, the SLA provides a sponsor with a means to hold the PBM/FDR accountable for failure to provide agreed upon services. As part of the PBMA, Smart negotiated such an SLA with Benecard.[56] The SLA included as part of the PBMA listed implementation milestones and ongoing service level expectations in the areas of account management, beneficiary services and operations and claims administration.[57]

[53] Department of Health and Human Services; Enterprise Performance Life Cycle Framework Practices Guide: Service Level Agreement / Memorandum of Understanding.
[54] Ibid.
[55] PBMA, Exhibit F (SMT3111363 - SMT3111368); PBMA, Section 7.2 (SMT0311331 - SMT0311332)
[56] PBMA, Exhibit F (SMT3111361 - SMT3111368)
[57] Ibid.

38. ***Review of the FDR's policies and procedures:*** An FDR's policies and procedures ("P&Ps"), business requirement documents ("BRDs")[58], and desktop procedures[59] provide the guidelines and workflows for how specific tasks should be performed. A sponsor's review of a contracted FDRs' P&Ps and related materials is an important oversight activity because these documents outline the principles, rules, and guidelines adopted by the organization that govern how the FDR will perform their contracted services. In assessing a company's approach to compliance, an important area to consider is the company's written P&Ps, in order to ensure a company's commitment to compliance with applicable regulations.[60]

39. Smart began to review Benecard's policies and procedural documents, including Benecard's desktop procedures and its system's business requirements documents, months prior to the plan launch date[61]. As Danielle Panich testified, Smart stated that it provided feedback to Benecard on any document that Smart believed was deficient or would give rise to non-compliance for Benecard to correct and update.[62] Reviewing P&Ps is a fundamental

[58] A business requirements document (BRD) details the business solution for a project including the documentation of customer needs and expectation (Six Sigma)

[59] A desktop procedure includes work instructions that should detail how to accomplish a specific task.

[60] U.S. Department of Health and Human Services, Office of Inspector General, "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731, May 5, 2003. ("Implementing written policies and procedures" listed as the first of "seven elements that have been widely recognized as fundamental to an effective compliance program").

[61] BC 0166333

[62] Deposition of Danielle Panich 44:12 – 45:24

step in assessing a vendor's compliance and is an industry standard process for providing oversight of a FDR[63].

40. I understand that Benecard is arguing that its P&Ps, desktop procedures, and BRDs contain its detailed procedures and system logic for formulary administration and coverage determinations, appeals and grievances (CDAG), and were reviewed by Smart. Further, I understand that Benecard is arguing that because Smart reviewed these materials, Smart should have been on notice of potential compliance issues arising from Benecard's administration of formulary administration and CDAG, processing described in the P&Ps, desktop procedures and BRDs. I have reviewed materials relating specifically to formulary administration and CDAG, and I believe this assertion is inaccurate.

41. The processes and procedures disclosed in Benecard's P&Ps, desktop procedures, and BRDs that I reviewed include correct content, and these documents are consistent with CMS requirements[64]. Smart's approval of those documents would not have put Smart on notice of Benecard's future non-compliance with Medicare Part D requirements, nor did it justify the many problems with formulary administration and CDAG that later arose and were identified by both Smart and CMS. Even if Benecard's P&Ps, desktop procedures, and BRDs were reviewed by Smart and deemed correct, Benecard may still have

[63] Medicare Part D PDBM Chapter 9, Section 50.1.3.
[64] Medicare Part D PDBM Chapter 6 & Chapter 18.

been non-compliant if it didn't apply (or code) those documents in its system properly. Application of the desktop procedures and BRDs was Benecard's responsibility, and Smart was limited in its review of Benecard's application of these documents because of the system access issues discussed in Opinion A.

42. ***Review of the program using CMS's Readiness Checklist:*** In September 2012, CMS released their Readiness Checklist for 2013.[65] The Readiness Checklist summarizes key operational requirements as established in statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, applications, and other advisory materials.[66] It functions as a summary of guidelines and requirements developed by CMS that provides plan sponsors a basis to gauge its readiness for compliant operations in the upcoming plan year. The Readiness Checklist is used industry wide as an operational oversight activity and is considered by plans and CMS as an important tool in determining the adequacy of a plan sponsor's operations before going live for the plan year[67]. Smart worked with Benecard to complete the Readiness Checklist and submit the Readiness Assessment, the CMS submission requirement based upon the Readiness Checklist, for its December 14, 2012 due date.[68]

[65] CMS Readiness Checklist, September 13, 2012 (2013_Readiness_Checklist_FINAL.pdf).
[66] Ibid.
[67] Ibid.
[68] HPMS "CY 2013 Medicare Advantage and Prescription Drug Plan Readiness Assessment Request," November 30, 2012.

43. ***Conduct operational and compliance testing:*** As explained in Opinion A, real-time access to the FDR's enrollment and claims system is a tool for enabling a plan sponsor's oversight because it provides the necessary visibility into the FDR's current operations and allows the plan sponsor to assess performance and compliance with Medicare program requirements. Real-time access also allows the plan sponsor to perform its oversight autonomously, giving the plan sponsor more control as to what, when, and how to perform its reviews.

44. Due to Benecard's failure to provide real-time access to Smart, Smart utilized alternative methods to conduct operational and compliance testing of Benecard. With respect to claims testing, prior to the start of the plan year, Smart attempted to audit plan set-up and claims adjudication[69]. Smart sent an employee to Benecard's facilities an average of two days per week from October 2012 through January 2013 to perform testing of the live enrollment and claim system[70]. However, the Smart employee was not allowed to perform real-time system testing of Benecard's Part D system.[71] Because Benecard would not permit live claims testing, Smart requested the testing be performed with dummy data (fictitious patients and fictitious claims). Benecard also refused to accommodate this request[72].

[69] Deposition of Cheryl Williams 53: 12 – 54: 10
[70] Deposition of Cheryl Williams 50: 13 – 51: 11
[71] Deposition of Cheryl Williams 51: 17 – 52: 1; 54: 8 - 10
[72] Deposition of Cheryl Williams 53: 4 – 55: 6

45. As an alternative to live testing, Benecard showed Smart screen shots of test claims processed through its commercial claim system since some claims adjudication components are similar to both commercial and Medicare Part D benefits.[73] Smart reviewed the Benecard provided screen shots of the testing performed in the commercial claim system and any results of Benecard's tests of the Part D system.[74]

46. Smart also arranged with Benecard to send some of its staff to Benecard's call center facility to perform an assessment of the call center's performance and to provide training to call center staff as needed. While at Benecard, Smart's staff was denied the opportunity to visit the call center, listen to any calls, or perform any training.[75] In lieu of performing reviews of live calls, Smart reviewed some sample recorded calls and provided feedback for training.[76]

47. Smart's alternative approaches were reasonable oversight in light of Benecard's inability to provide real-time access.

48. Smart also performed monthly retroactive audits as part of its oversight of Benecard.[77] These were referred to by Smart as "Monthly QA Reviews." One of the primary elements of the compliance guidelines outlined by CMS in Chapter 9 is that a plan sponsor

[73]Deposition of Cheryl Williams 198: 7 – 199: 19
[74] Ibid.
[75] Deposition of Stephanie Bayer 92: 12 – 93: 4
[76] Deposition of Danielle Panich 151: 17- 153: 20
[77] Smart P&P Comp-008 "Medicare Part D Compliance First Tier, Downstream and Related Entity Delegate Entity Oversight."

should establish an effective system for routine monitoring, auditing and identification of compliance risks including FDRs. Monthly QA Reviews for all enrollment related audit areas started in November 2012, after the onset of CMS' annual open enrollment period[78]. The Monthly QA Review included claims and benefit administration elements once the plan year began in January 2013.[79,80]

49. Given Benecard's failure to provide online, real-time access to enrollment and claims systems and data after the plan went live, Smart had to use alternative testing methods described in Opinion A to conduct its Monthly QA Reviews.[81] These alternative testing activities allowed Smart to perform the oversight of its first tier entity that CMS recommends. However, these alternatives were not ideal.

50. ***Employ effective lines of communication:*** Another guideline outlined in Chapter 9 of the Prescription Drug Benefit Manual on Compliance Program Guidelines is the establishment of effective lines of communication as it relates to the reporting of non-compliance. Smart implemented these lines of communication in a number of ways.

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[78] Summary for October 2012_ENR_DNR.docx (no Bates number).
[79] Audit Element Summary January.docx (no Bates number).
[80] As part of these reviews, Smart audited Benecard's formulary administration, coverage determinations, appeals, and grievances using the publically available CMS audit guidelines as their audit method and approach. When auditing other operational areas, Smart used the requirements put forth in the statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, applications, and other advisory materials to establish audit criteria and expected performance levels (Interview with Danielle Panich on March 29, 2016).
[81] Deposition of Danielle Panich 141:20 – 142:10

51. Smart employed the use of Corrective Action Plans (CAPs) to document, track, and communicate any identified areas of non-compliance[82]. Smart identified compliance issues through vendor self-reporting,[83] Smart directed oversight[84], and CMS identified issues. When discussing this process with a Smart Quality Assurance staff member, she told us that in order to facilitate vendor self-reporting, Smart developed a form allowing Benecard to report identified issues, the root cause and a plan for remediation.[85] Both vendor-self reported issues as well as issues identified by other means would lead Smart to issue a CAP for the corresponding issue. Smart tracked the status of the CAPs,[86] which would remain open until the audit area received successful results during subsequent audits.[87]

52. Smart held regular calls and meetings with Benecard to review plan performance, operational and compliance issues and corrective action plan remediation progress. As early as August 6, 2012 Smart held scheduled calls and meetings with Benecard[88] during which Smart created detailed project logs to support the agendas of these meetings. The project logs were updated following each meeting and shared with Benecard.[89,90] The use

[82] Smart P&P Comp-012 "Corrective Action Plan."
[83] Smart P&P Comp-062 "Self-Reporting of Compliance Issues from First Tier, Downstream and Related Entities (FDR)."
[84] Smart P&P Comp-008 "Medicare Part D Compliance First Tier, Downstream and Related Entity Delegate Entity Oversight."
[85] Interview with Danielle Panich, March 29, 2016.
[86] Smart P&P Comp-012 "Corrective Action Plan."
[87] Interview with Danielle Panich, March 29, 2016.
[88] Deposition of Danielle Panich 91: 11 – 21; 110: 10-14
[89] Interview with Danielle Panich, March 29, 2016.

of CAPs, vendor self-reporting, and regular calls and meetings demonstrates Smart's means of creating open lines of communication between itself and Benecard. These lines of communication are the means by which Benecard and Smart could discuss compliance issues, remediation efforts, and program changes.

53. It is my opinion that although Smart took the correct steps that CMS would have expected in terms of providing oversight and monitoring of Benecard, Smart encountered challenges in its oversight activities, some of which limited the activities' effectiveness. The most significant challenges were Benecard's failure to provide meaningful real-time access to enrollment and claims systems and data (Opinion A) and Smart's inability to fully test the Part D system prior to going live (Opinion A).

54. As a result of these challenges, testing was limited, and Smart did not have enough performance data to justify a PBM change.[91] Based on the expected implementation timelines as outlined in the agreed to SLAs (benefits set-up completion by August 15, 2012, accuracy of clinical programs set-up by September 1, 2012, and accurate claims test results by

[90] Project logs outlined for each task: the start and projected end date, the percentage of the project that was complete at that given time, the actual date of completion for finished projects, the project owner, and details surrounding project updates (BC 0147757; BC 1047758).

[91] Deposition of Cheryl Williams 201: 19 – 202: 6 " I would say it takes nine months to a year to successfully implement a new PBM."

December 2012),[92] Smart would not have had enough performance data as of the needed timeframe to determine a change in PBM was needed.

55. I understand that Benecard is claiming that it was adjudicating claims in compliance with the CMS approved formulary and that Smart should have anticipated improper claim rejections as they had access to the formulary and were responsible for plan oversight. Benecard is also claiming that Smart is at fault for the improper claim rejections for having not identified issues in the formulary prior to its submission. I believe this argument to be incorrect.

56. First, it is unlikely that CMS would have approved a formulary that did not comply with regulatory requirements. CMS has a rigorous formulary review process that was described by the Acting Administrator of CMS when testifying before Congress in 2007. She stated, "The MMA requires CMS to review Part D formularies to ensure that beneficiaries have access to a broad range of medically appropriate prescription drugs to treat all disease states. CMS relies on stringent formulary requirements, overseen through a comprehensive, multi-step review process, to help ensure beneficiaries have access to covered Part D drugs. As a condition of participation in Part D, sponsors must submit their plan formularies for CMS review and approval. CMS considers covered drugs as well as utilization management techniques in reviewing plan formularies. If CMS reviewers find that a plan's formulary could

[92] PBMA, Exhibit F, Section A (SMT3111361 - SMT3111363)

substantially discourage enrollment by certain types of beneficiaries or otherwise violates Part D program requirements, that formulary will not be accepted and if unchanged, the plan is not eligible for a Part D contract."[93]

57. In addition, CMS audits the plan using the plan sponsor's approved formulary, so only variations between the CMS approved formulary and the implementation of that formulary would be cited in an audit[94]. This means the audit should not have uncovered any issues if the formulary had been administered in accordance with the CMS approved formulary. Benecard itself acknowledged that its improper implementation of the CMS approved formulary in its system configuration caused these rejections.[95]

58. ***Opinion C: Benecard did not operate in a manner compliant with Medicare Part D program requirements.***

59. Benecard displayed non-compliant behavior while administering Smart's eligibility and enrollment operations during the annual open enrollment period for 2013 (between October 15th and December 7th, 2012[96]). Benecard's non-compliant behavior continued through the start of the plan year and into its administration of the plan's benefits.

[93] Testimony Statement by Leslie V. Norwalk, Acting Administrator, Centers for Medicare & Medicaid Services on "The Medicare Prescription Drug Benefit: Beneficiary Protections and Plan Oversight before Committee on Ways and Means, Subcommittee on Health U.S. House of Representatives," June 21, 2007.

[94] CMS audit protocol, as listed in the Formulary Administration section of the Part D Formulary and Benefit Administration (FA) Program Area Audit Process and Data Request document, lists the audit's compliance standard as whether the claim adjudication process follow the approved CMS formulary.

[95] CAP 13-0008 "Inappropriate Claim Adjudication Regarding Formulary Tier Placement," February 6, 2013 (CAP_13-0008.PDF).

[96] CMS Medicare Open Enrollment 2013 presentation.

An initial indication that Benecard was not administering benefits appropriately was the high volume of rejected claims[97]. Benecard identified 57,610 rejected claims for issues found from March to August 2013[98]. In addition to the high volume of rejected claims, Smart also ranked number one in volume of Medicare received complaints, CTMs[99], compared to all other Part D plans;[100] and the volume of grievances received by Smart was 7 times that of other Part D plans[101]. Benecard experienced operational non-compliance in the following areas of administration:

a. Formulary administration;

b. Call center operations;

c. Administration of Coverage Determinations, Appeals and Grievances;

d. Eligibility and enrollment; and

e. Coordination of benefits[102].

60. Despite opportunities to remediate the non-compliant behavior, Benecard was unable to correct all issues and provide its contracted services in compliance with Medicare Part D program requirements. I've included a brief summary of key issues for each area below.

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[97] HPMS "CMS in the Best Practices and Common Findings Memo #2 from 2012 Program Audits," July 30, 2013.
[98] SMT00166095
[99] Complaints tracking module
[100] SMT00175007 - SMT00175008
[101] BC 0286420
[102]SMT00175005 – SMT00175008

a. Formulary administration: Smart delegated formulary administration to Benecard.[103] This means that Benecard would have needed to configure its claim system to allow for the adjudication of claims at the point of sale in accordance with the formulary, or covered drug list, approved by CMS. Smart's formulary not only listed the drugs the plan was to cover, but also any associated utilization management (UM) measures (Prior Authorization(PA), Quantity Limits (QL) and Step Therapy(ST))[104] for applicable drugs[105]. Part of formulary administration also includes other functions, such as: determining whether a claim should be covered under Part D, determining whether the beneficiary qualified for a transition supply, and applying logic that prevents the underutilization and overutilization of medication[106].

In early January 2013, Smart was reviewing rejected claims three to four times daily to determine appropriateness of the reject and initiate remediation on the claims as necessary.[107] As early as January 11, 2013, CMS had already reviewed Smart's rejected claims, identified issues with quantity limits and unapproved prior authorizations and required Smart perform a more in-depth analysis to determine the root cause(s) for

[103] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 19 B).
[104] Refer to Appendix A.
[105] SMT00042216; SMT00042218
[106] Medicare Part D PDBM Chapter 6.
[107] SMT00121502

certain rejected claims.[108] CMS issued a formal notice to Smart via email on March 18, 2013 listing eight deficiencies relating to the formulary services delegated to and performed by Benecard identified during the CMS audit that required Immediate Corrective Action.[109] The April 23, 2013 sanction letter discussed similar failures regarding (1) transition supplies of prescription drugs, (2) providing coverage for protected class drugs, and (3) applying an unapproved quantity limit to a prior authorization.[110] CMS cited the previously discussed issues surrounding Benecard's delegated formulary administrative services as needing immediate corrective action on May 10, 2013,[111] and again one month later on June 13, 2013.[112]

b. ***Call center operations***: The call center operations were delegated to Benecard[113]. On January 3, 2013, CMS tested the customer service and pharmacy technical help desk, and discovered that Benecard (1) failed to operate a toll free customer service telephone number and (2) did not comply with the CMS allowed maximum wait time of 2 minutes for both phone lines.[114] A June 13, 2013 list of Current High Level Issues identified by CMS still included issues with customer service representatives, call log observations,

[108] SMT00121502 - SMT00121503
[109] SMT00335619 - SMT00335621
[110] SMT00002983 - SMT00002993
[111] SMT00003308 - SMT00003314
[112] SMT00175004; SMT00175005 - SMT00175008
[113] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 19 E).
[114] SMT00025484 - SMT00025486

and beneficiary communications.[115] Benecard admitted that its call center made mistakes because of poor training and lack of understanding the CMS rules.[116]

c. Administration of Coverage Determinations, Appeals and Grievances (CDAG): The Medicare Part D program establishes certain beneficiary rights and protections.[117] These rights include the beneficiary's entitlement to file a grievance, coverage determination, and/or appeal.[118]

CDAG services were delegated to Benecard.[119] By January 4, 2013, CMS had requested that Smart provide them with reporting on rejected claims[120], and on January 11th CMS issued a formal compliance notice to Smart requesting a root cause analysis and remediation for inappropriately rejected claims.[121] The April 23, 2013 sanction letter described 14 different failures for Part D coverage determinations and appeals[122]. One issue identified in this letter related to the plan's inability to meet the CMS timeliness requirements of coverage determination and appeal case decisions. In addition, the

[115] SMT00175005 - SMT00175008
[116] BC0682745 – BC0682746; SMT00161945 – SMT00161948
[117] Testimony Statement by Leslie V. Norwalk, Acting Administrator, Centers for Medicare & Medicaid Services,"The Medicare Prescription Drug Benefit: Beneficiary Protections and Plan Oversight before Committee on Ways and Means, Subcommittee on Health U.S. House of Representatives," June 21, 2007.
[118] Refer to Appendix A.
[119] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 19 C).
[120] SMT00033351
[121] SMT0012502 – SMT0012503
[122] SMT00002983 - SMT00002993

volume of cases forwarded to the Independent Review Entity (IRE)[123] because of the plan's failure to meet required timeframes for rendering decisions was also cited.[124] In July 2013, Benecard still had issues with rendering timely decisions, and CMS provided statistics showing that 286 out of 300 cases sent to the IRE during June 2013 were auto-forwarded because of untimely decisions.[125]

d. Eligibility and enrollment: Eligibility and enrollment services were delegated to Benecard.[126] Eligibility and enrollment issues arose for Smart prior to the launch of the plan. From November 9 – December 4, 2012, Benecard failed to process certain Online Enrollment Center (OEC) files resulting in untimely enrollment processing and issuance of member material for 879 beneficiaries.[127] On April 23, 2013, Smart was sanctioned and suspended from marketing and enrollment activities as a result of their March audit.[128] Enrollment administration continued to be a concern for CMS as it was cited as a Current High Level Issue in an email from CMS on June 13, 2013.[129]

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[123] An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations and cases unable to be decided upon in the CMS required timeframes.
[124] SMT00002989 - SMT00002990
[125] SMT00177488
[126] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 19 A).
[127] CAP 12-0008 (CAP 12-0008.pdf).
[128] SMT00002991 – SMT00002992
[129] SMT00175005 - SMT00175008

e. ***Coordinating Benefits:*** Coordination of benefits services was delegated to Benecard.[130] MMA regulations require that plan sponsors coordinate benefits appropriately with SPAPS[131] and other providers of prescription drug coverage[132]. On January 7, 2013, Smart sent an email to CMS describing an issue arising from Benecard's inability to coordinate claims with the Missouri State Pharmacy Assistance Program (MO SPAP).[133] As of January 14, 2013, an email from Benecard indicated that the issue had not been remediated.[134] CMS also included issues with COB in its June 2013 notification of Current High Level Issues.[135] CMS cited receipt of a call from the Kidney Healthcare Program (aka Texas SPAP) who contacted CMS looking to identify someone at Smart who could assist with initiating coordination of benefits processes for its members. The Texas SPAP contacted CMS because it had attempted to contact Smart, but received no response.[136]

61. Benecard failed to maintain compliance since it started operations on behalf of Smart in October 2012. Benecard's compliance issues were so extensive that even its

[130] Smart v. Benecard: Complaint, filed June 8, 2015 (Paragraph 19).
[131] State Pharmaceutical Assistance Programs
[132] 42 CFR §423.464
[133] SMT00002566 - SMT00002567
[134] BC 0380983 - BC 0380984
[135]SMT00175008
[136] Ibid.

remediation efforts could not address all of the issues in its operations as demonstrated by the repeated occurrences of similar failures.

62. ***CMS's sanction of Smart does not mean that Smart is the unilateral cause of non-compliance.*** When providing official communication to the plan, it is customary for CMS to address the plan sponsor and not its delegated entities.[137] I understand that Benecard has argued that because the sanctions letter does not mention Benecard by name (and instead refers only to Smart), that Smart must have been responsible for all of the actions that led to the sanction. This is an incorrect assumption.

63. CMS' contract is with the plan sponsor, and CMS holds no contract directly with FDRs administering on behalf of the plan sponsor. CMS states in Chapter 9, specifically, "CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements."[138] Therefore, it is expected that all communication regarding the plan will be addressed to the plan sponsor and not a delegated FDR, even if the FDR is responsible for the operational area or incident of non-compliance being addressed by CMS.

64. That is why visibility into a FDR's operations via complete and reliable real-time access to enrollment and claims systems and data is so crucial. The plan sponsor needs to know exactly what is happening with the benefit administration, exactly when it is happening

[137]Centers for Medicare and Medicaid Services Part C and Part D Enforcement Actions, (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.html).

[138] Medicare Part D PDBM Chapter 9, Section 40.

because the plan sponsor is the party to whom CMS will look if there is noncompliance. So, CMS' decision not to mention Benecard directly, but address all issues to Smart, is in line with CMS' normal process and does not mean that any of Smart's direct actions led to the sanction.

V. CONCLUSION

65. As described in this report, I was asked to evaluate the following: (1) whether Benecard provided real-time enrollment and claims system access that is consistent with industry standards and sufficient for Smart to perform administrative and oversight tasks under its agreement with CMS; (2) whether Smart performed oversight of Benecard as a first tier entity consistent with CMS' guidelines and industry norms; and (3) whether Benecard operated in a manner consistent with Medicare Part D program requirements.

66. As the above opinions set forth, I conclude that Benecard did not provide real-time system access that is typical within the market or necessary for Smart to perform administrative and oversight tasks. I conclude that Smart did conduct oversight of Benecard to the best of its ability given this lack of real-time system access. Further, I conclude that Benecard did not operate in compliance with Medicare Part D requirements. The pattern of Benecard operating in non-compliance with CMS requirements, and Smart's lack of visibility into Benecard's operations to gauge Benecard's performance, led to repeated occurrences of the

same or similar deficiencies. Ultimately, Benecard's repeated non-compliance with Medicare Part D program requirements and Smart's expectations led to CMS' sanctions against Smart, which contributed significantly to the eventual sale of the plan.

Attachment 1

NAVIGANT

Erin V Costell

Director

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Professional Summary

Erin Costell is a Director leading the Pharmacy Compliance service sector within Navigant's Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations practice. Erin has sixteen years of experience in healthcare benefits consulting and administration focusing on the managed Medicare market.

Erin's clients have included corporate/commercial plan sponsors, governmental agencies, pharmacy benefit managers, government program plan sponsors, pharmacies and Business Process Outsourcing (BPOs) companies. Erin's service experience includes a wide array of systems, operations and compliance work allowing Erin to assess compliance with program requirements while also providing workable system, process and resource solutions.

Areas of Expertise

- **Compliance:** Provides subject matter and technical expertise across the full spectrum of compliance and monitoring activities for government healthcare programs.
- **Operations:** Provides insight on how to align process optimization and compliance. Specializes in assessing operational and compliance gaps and provides strategy around systems, staffing and automation.
- **Systems:** Delivers insight into healthcare front end, claim, UI and BI systems and software performance and compliance.

Professional Experience

Compliance

- **CMS "Mock" Program Audits** - Erin has performed CMS Mock Audits for Medicare Advantage + Prescription Drug Plans (MAPD), Medicare Prescription Drug Plans (PDPs) and Medicare Special Needs Plans (SNPs). Mock Audits were performed using CMS' annual audit guides and included document review and data testing as if under an actual CMS audit. Erin has led comprehensive mock audits, covering all program operational areas, as well as targeted audits.
- **CMS Audit Support and Corrective Action Plan Development** - Erin has supported clients under CMS audit as well as led internal audit response teams. Erin is familiar with the audit process

NAVIGANT

Erin V Costell
Director

including documentation and data requirements. Erin has led and provided oversight of the development of Corrective Action Plans (CAPs) in response to audit findings.

- **Transactional Audits** - Erin has performed transactional audits of commercial and government program plan sponsors, corporate/Taft Hartley plan sponsors and Pharmacy Benefit Managers (PBMs). Erin has led and/or performed the data testing to validate compliance with contractual terms and/or regulatory requirements. Erin has performed the following types of transactional audits:
    - Pharmacy claim adjudication and payment accuracy;
    - Prescription Drug Event (PDE) data creation accuracy;
    - Financial Information Reporting (FIR) integration into accumulators;
    - Enrollment maintenance and use in benefit administration;
    - Rebate payment accuracy.

Operations

- **Operational Compliance Assessments and Recommendations** - Erin has assessed operational compliance on behalf of health plans/PBMs, BPOs/claims payers and pharmacies. Erin has also designed system and process changes to achieve compliance while maximizing automation and efficiency.
- **Corrective Action Plan Implementation** – Erin has helped develop and implement required system, software, process, staffing and/or documentation changes for payers, providers and BPOs to bring operations into compliance with government program requirements.
- **PBM Bidding and Contracting** - Erin has directed and functioned as the business analyst for PBM bidding projects performing claim re-pricing, financial comparisons and reviews of contractual terms to determine the placement of PBM services.
- **Cost Projections / Cost Containment Strategies**- Erin functioned as the business analyst in the development of annual cost projections and self-insured premium rate equivalents. Erin served as a data analyst in the development of a pharmacy benefit rate manual which was sold to a mid-sized PBM for use in developing insured premium rates. Erin also performed claim studies to identify abnormal spending and recommended clinical programs or plan design changes to reduce healthcare costs.

Systems

- **System and Software Assessments** – Erin has evaluated systems and software configuration, functionality and performance for healthcare front end, claims, UI and BI systems and identified

NAVIGANT

Erin V Costell

Director

compliance gaps and areas of improvement.

- **KPI Metrics and Operational Reporting** - Erin has identified KPIs and designed operational reporting and performance dashboards for varied areas of healthcare administration including premium payments/collections, eligibility and enrollment, claims (paid and rejected), COBC enrollment and PDE rejects.

- **Eligibility and Enrollment Software Solution Development and Support** - Erin functioned as the system analyst and led the development of a Medicare enrollment system and Part D financial reporting software package. As of 2013, the software serviced just under 1M Medicare lives. As part, Erin participated in the development of systems documentation, operational procedures and training materials

Work History

Navigant Consulting	2014 - Present
GPS LLC	2007 - 2014
IPC INC	2005 - 2007
Buck Consultants	2003 – 2005
HealthScope Benefits (formerly CNA Insurance)	2000 – 2003

Education

Bachelors of Science, Economics	Pennsylvania State University, Smeal College of Business Administration

Presentations

- Costell, Erin. “What a CMS Audits Means to the Medicare Plan’s Vendors - Compliance for First Tier, Downstream & Related Entities.” CBI Pharmacy Benefit Oversight and Compliance Congress. Chicago, IL. 12 November 2014
- Costell, Erin. “Strategies and Tools to Effectively Manage FDR Audit and Oversight” CBI Pharmacy Benefit Oversight and Compliance Congress. Scottsdale, AZ. 12 November 2015
- Costell, Erin. DeAngelis, Dorothy. Brecht, Pamela. Marshall, Laura Colombell (panel chair). “Trends and Hot Topics in Health Law Litigation.” ABA Section of Litigation. Regional CLE Workshop. Los Angeles, CA. 3November 2015

NAVIGANT

Erin V Costell

Director

Publications

- Costell, Erin. "*Medicare Part D and the Plan Sponsor: What You Don't Know Can Hurt You and Your Bottom Line"* 2007. HR Management

Testimony History

- N/A

Attachment 2

Smart v. Benecard
Documents Considered

Bates Numbered Documents

1.	SMT00003096	SMT00003096
2.	SMT00003095	SMT00003095
3.	SMT00003308	SMT00003315
4.	SMT00883515	SMT00883515
5.	SMT00339488	SMT00339490
6.	SMT00388715	SMT00388717
7.	SMT00157645	SMT00157645
8.	SMT00169424	SMT00169427
9.	SMT00008754	SMT00008760
10.	SMT00419751	SMT00419756
11.	SMT00175005	SMT00175008
12.	SMT00175004	SMT00175004
13.	SMT00393028	SMT00393040
14.	SMT00450375	SMT00450431
15.	SMT00450373	SMT00450374
16.	SMT00390860	SMT00390866
17.	SMT00177488	SMT00177489
18.	SMT00390920	SMT00390920
19.	SMT00149165	SMT00149170
20.	SMT00149172	SMT00149173
21.	SMT00149174	SMT00149177
22.	SMT00149162	SMT00149164
23.	BC0660006	BC0660006
24.	BC0660007	BC0660008
25.	BC0660009	BC0660021
26.	BC0660022	BC0660022
27.	BC0660023	BC0660028
28.	BC0660029	BC0660038
29.	BC0660039	BC0660045
30.	BC0660046	BC0660046
31.	BC0460570	BC0460572
32.	BC0241843	BC0241843
33.	BC0241844	BC0241846
34.	BC0241847	BC0241849
35.	BC0659953	BC0659953
36.	BC0659954	BC0659955
37.	BC0659956	BC0659969
38.	BC0659970	BC0659970
39.	BC0496995	BC0496995
40.	BC0496996	BC0496996
41.	BC0496997	BC0497025

Smart v. Benecard
Documents Considered

42.	BC0497026	BC0497057
43.	BC0330343	BC0330343
44.	BC0330344	BC0330344
45.	BC0330345	BC0330363
46.	BC0660047	BC0660047
47.	BC0232377	BC0232378
48.	BC0674981	BC0674981
49.	BC0674982	BC0675011
50.	SMT00116341	SMT00116341
51.	SMT00116342	SMT00116372
52.	SMT00046025	SMT00046026
53.	BC0683141	BC0683143
54.	BC 0722815	BC 0722815
55.	BC 0722880	BC 0722880
56.	BC 0722898	BC 0722898
57.	BC 0722900	BC 0722900
58.	BC 0722901	BC 0722901
59.	BC 0722917	BC 0722917
60.	BC 0722933	BC 0722933
61.	BC 0722959	BC 0722959
62.	BC 0723015	BC 0723015
63.	BC 0723016	BC 0723016
64.	BC 0723017	BC 0723017
65.	BC 0723018	BC 0723018
66.	BC 0723143	BC 0723143
67.	BC 0723144	BC 0723144
68.	BC 0723155	BC 0723155
69.	BC 0723202	BC 0723202
70.	BC 0723211	BC 0723211
71.	BC 0723214	BC 0723214
72.	BC 0723219	BC 0723219
73.	BC 0723220	BC 0723220
74.	BC 0723237	BC 0723237
75.	BC 0723238	BC 0723238
76.	BC 0723239	BC 0723239
77.	BC 0723240	BC 0723240
78.	BC 0723316	BC 0723316
79.	BC 0723442	BC 0723442
80.	BC 0723451	BC 0723451
81.	BC 0723834	BC 0723834
82.	BC 0723842	BC 0723842
83.	BC 0723879	BC 0723879

Smart v. Benecard
Documents Considered

84.	BC 0723880	BC 0723880
85.	BC 0723957	BC 0723957
86.	BC 0723958	BC 0723958
87.	BC 0723959	BC 0723959
88.	BC 0723961	BC 0723961
89.	BC 0723973	BC 0723973
90.	BC 0723976	BC 0723976
91.	BC 0723977	BC 0723977
92.	BC 0723978	BC 0723978
93.	BC 0723980	BC 0723980
94.	BC 0723981	BC 0723981
95.	BC 0723986	BC 0723986
96.	BC 0723988	BC 0723988
97.	BC 0723989	BC 0723989
98.	BC 0723994	BC 0723994
99.	BC 0723995	BC 0723995
100.	BC 0723998	BC 0723998
101.	BC 0724008	BC 0724008
102.	BC 0724009	BC 0724009
103.	BC 0724012	BC 0724012
104.	BC 0724042	BC 0724042
105.	BC 0724069	BC 0724069
106.	BC 0724070	BC 0724070
107.	BC 0724071	BC 0724071
108.	BC 0724072	BC 0724072
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110.	BC 0724074	BC 0724074
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113.	BC 0724078	BC 0724078
114.	BC 0724079	BC 0724079
115.	BC 0724080	BC 0724080
116.	BC 0724081	BC 0724081
117.	BC 0724082	BC 0724082
118.	BC 0724083	BC 0724083
119.	BC 0724086	BC 0724086
120.	BC 0724087	BC 0724087
121.	BC 0724089	BC 0724089
122.	BC 0724090	BC 0724090
123.	BC 0724212	BC 0724212
124.	BC 0724213	BC 0724213
125.	BC 0724219	BC 0724219

Smart v. Benecard
Documents Considered

126.	BC 0724453	BC 0724453
127.	BC 0724559	BC 0724559
128.	BC 0724621	BC 0724621
129.	BC 0724631	BC 0724631
130.	SMT00222264	SMT00222264
131.	SMT00222265	SMT00222268
132.	SMT00222868	SMT00222868
133.	SMT00222869	SMT00222870
134.	SMT00454521	SMT00454521
135.	SMT00454522	SMT00454523
136.	SMT00454525	SMT00454527
137.	SMT00454529	SMT00454529
138.	SMT00042214	SMT00042215
139.	SMT00042216	SMT00042217
140.	SMT00042218	SMT00042218
141.	SMT00042219	SMT00042219
142.	SMT00039236	SMT00039237
143.	SMT00039238	SMT00039238
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147.	SMT00039227	SMT00039231
148.	SMT00006569	SMT00006571
149.	SMT00311523	SMT00311525
150.	SMT00016481	SMT00016481
151.	SMT00016496	SMT00016496
152.	SMT00045979	SMT00045980
153.	SMT00219953	SMT00219953
154.	SMT00227617	SMT00227618
155.	SMT00075423	SMT00075424
156.	SMT00075426	SMT00075429
157.	SMT00096891	SMT00096892
158.	SMT00096893	SMT00096893
159.	SMT00097650	SMT00097651
160.	SMT00272174	SMT00272174
161.	SMT00279476	SMT00279476
162.	BC 0084755	BC 0084757
163.	SMT00166091	SMT00166094
164.	SMT00311316	SMT00311369
165.	SMT00002983	SMT00002993
166.	SMT00867106	SMT00867108
167.	SMT00867103	SMT00867105

Smart v. Benecard
Documents Considered

168.	SMT00867101	SMT00867102
169.	SMT00311577	SMT00311578
170.	SMT00000942	SMT00000943
171.	SMT00669038	SMT00669040
172.	SMT00669036	SMT00669036
173.	SMT00033351	SMT00033351
174.	SMT00025484	SMT00025488
175.	SMT00002568	SMT00002568
176.	SMT00002566	SMT00002567
177.	SMT00025579	SMT00025581
178.	SMT00025655	SMT00025657
179.	BC 0380983	BC 0380984
180.	SMT00121498	SMT00121503
181.	BC 0049627	BC 0049627
182.	SMT00033557	SMT00033558
183.	SMT00033636	SMT00033640
184.	SMT00025852	SMT00025853
185.	SMT00331425	SMT00331425
186.	SMT00693015	SMT00693016
187.	SMT00018636	SMT00018641
188.	SMT00026751	SMT00026755
189.	BC 0282654	BC 0282656
190.	SMT00693077	SMT00693078
191.	SMT00336692	SMT00336693
192.	SMT00152357	SMT00152359
193.	SMT00166090	SMT00166090
194.	SMT00160567	SMT00160568
195.	SMT00335623	SMT00335631
196.	SMT00335619	SMT00335622
197.	SMT00866944	SMT00866945
198.	SMT00149851	SMT00149852
199.	SMT00054274	SMT00054275
200.	SMT00335632	SMT00335632
201.	SMT00027961	SMT00027963
202.	SMT00024631	SMT00024631
203.	SMT00020419	SMT00020419
204.	SMT00311599	SMT00311600
205.	SMT00121475	SMT00121476
206.	SMT00006798	SMT00006798
207.	SMT00004704	SMT00004707
208.	SMT00027008	SMT00027008
209.	SMT00866731	SMT00866731

Smart v. Benecard
Documents Considered

210.	SMT00020903	SMT00020904
211.	SMT00312332	SMT00312336
212.	BC 0286420	BC 0286420
213.	SMT00151069	SMT00151070
214.	SMT00070841	SMT00070841
215.	SMT00070842	SMT00070843
216.	BC 0176105	BC 0176105
217.	BC 0176106	BC 0176106
218.	BC 0176528	BC 0176528
219.	BC 0176529	BC 0176529
220.	SMT00069622	SMT00069622
221.	SMT00069623	SMT00069623
222.	BC 0147757	BC 0147757
223.	BC 0147758	BC 0147758
224.	BC 0167201	BC 0167201
225.	BC 0167202	BC 0167202
226.	BC 0165107	BC 0165107
227.	BC 0165108	BC 0165108
228.	SMT00036906	SMT00036906
229.	SMT00036907	SMT00036907
230.	SMT00037426	SMT00037426
231.	SMT00037427	SMT00037427
232.	SMT00148896	SMT00148896
233.	BC 0166333	BC 0166335
234.	BC 0166336	BC 0166336
235.	SMT00000965	SMT00000966
236.	SMT00033958	SMT00033958
237.	SMT00033959	SMT00033959
238.	SMT00033960	SMT00033960
239.	SMT00039934	SMT00039934
240.	SMT00039935	SMT00039935
241.	SMT00039936	SMT00039957
242.	SMT00039958	SMT00039958
243.	SMT00039959	SMT00039959
244.	SMT00039960	SMT00039960
245.	SMT00039961	SMT00039964
246.	SMT00039965	SMT00039967
247.	SMT00042219	SMT00042219
248.	SMT00042220	SMT00042225
249.	SMT00039242	SMT00039242
250.	SMT00039110	SMT00039225
251.	SMT00039226	SMT00039226

Smart v. Benecard
Documents Considered

252.	SMT00331426	SMT00331426
253.	SMT00166095	SMT00166095
254.	SMT00097496	SMT00097498
255.	SMT00026485	SMT00026486
256.	BC 0212761	BC 0212761
257.	BC 0381097	BC 0381097
258.	BC 0384662	BC 0384662
259.	BC 0682745	BC 0682745
260.	SMT00161945	SMT00161948

Smart v. Benecard
Documents Considered

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261.	Documentation surrounding Corrective Action Plans (CAPs) 12-0001 – 12-0013 issued by Smart in 2012, and CAPs 13-0001 – 130028 issued by Smart in 2013.
262.	Smart Retroactive Monthly Audits. These audits took place between October 2012 – June 2013, and included oversight for the following areas: Agent, BAE, Billing, Call Center, CDA, Claims Review, COB, CTM, Enrollment, FIRs, Formulary, Grievance, LEP, MMR, MPWR, PWO, Transition, 700 Series, and all elements.
263.	CY 2013 Part D Readiness Documentation Volumes 1 & 2, including information on the following topics: Administration-Benefit Protection, BAE-LIS, Claims Processing-Transition, COB-Data Report-Auto TROOP, Compliance-FWA, Contracting – Oversight, Customer Service, Enrollment disenrollment – Premium Billing, Grievance Coverage Determination Appeals, Management-Org Structure, Marketing-Agent, Reporting, Systems-Data – Connectivity.
264.	Deposition of Cheryl Williams, March 25, 2016.
265.	Deposition of Danielle Panich, February 25, 2015.
266.	Deposition of Jeffery Reed, March 23, 2016.
267.	Deposition of Tammy Cappadonna, February 23, 2016.
268.	Deposition of Stephanie Bayer, March 2, 2016.
269.	Appeals Process.pdf
270.	Claims Adjudication (POS).pdf
271.	Claims Processing Transition.pdf
272.	Compliance Review Claims Determinations and Appeals Apprvd.pdf
273.	Compliance Transition Fill.pdf
274.	Determinations and Appeals.pdf
275.	Grievance Reporting and Oversight (8-24-2012).pdf
276.	Grievance-Coverage Determinations-Appeals.pdf
277.	Part B vs D policy 20.2000.27.pdf
278.	Transition Policy for Part D 20 2000 03.pdf
279.	Expert BRD Index-Send.xlsb
280.	006b - CMS formulary excel.XLSX
281.	002 - PBMA Signature page.pdf
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283.	8.13.13 email to Babette.PDF
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Smart v. Benecard
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287.	Medicare Advantage and Prescription Drug Plan Audit Process Overview, Attachment X.
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289.	CMS, "2015 Capitated Financial Alignment Application." 2015, § 2.9.
290.	CMS, "How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules." October 2015.
291.	CMS, Medicare Part D Prescription Drug Benefit Manuals (PDBM).
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293.	Department of Health and Human Services; Enterprise Performance Life Cycle Framework Practices Guide: Service Level Agreement / Memorandum of Understanding.
294.	Health Plan Management System "Release of Notice of Intent to Apply for Contract Year 2013 Medicare Advantage (Part C) and Prescription Drug Benefit (Part D) Contracts, and Related CY 2013 Application Deadlines," October 21, 2011.
295.	HPMS "CMS in the Best Practices and Common Findings Memo #2 from 2012 Program Audits," July 30, 2013.
296.	HPMS "Contract Year 2013 Medicare Advantage Organization, Prescription Drug Plan and 1876 Cost Plan Readiness Checklist," September 13, 2012.
297.	HPMS "CY 2013 Medicare Advantage and Prescription Drug Plan Readiness Assessment Request," November 30, 2012.
298.	"How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules."
299.	Interview with Danielle Panich, March 29, 2016.
300.	Johns Hopkins EHP, "Quantity Limits."
301.	Lucia Giudice, Director and Tom Longar, Sr. Associate (PwC Health Industries – Payer), HCCA Part D Compliance Conference, PBM Delegation and Oversight, December 11, 2007.
302.	National Health Policy Forum "The Medicare Drug Benefit (Part D)", January 4th, 2016.
303.	Neil MacKinnon and Ritu Kumar, "Prior Authorization Programs: A Critical Review of the Literature." Journal of Managed Care Pharmacy 7 (July/August 2001).
304.	Office of Inspector General, "Memorandum Report: Medicare Part D Prescription Drug Plan Sponsor Internet Web Sites: Content and Accessibility. "October 17, 2007.
305.	Smart Insurance Company's Complaint against Benecard Services, Inc., filed June 8, 2015.
306.	Thomas Gryta, "What is a 'Pharmacy Benefit Manager?'," *The Wall Street Journal*, July 21, 2011.
307.	Testimony Statement by Leslie V. Norwalk, Acting Administrator, Centers for Medicare & Medicaid Services, "The Medicare Prescription Drug Benefit: Beneficiary Protections and Plan Oversight before Committee on Ways and Means, Subcommittee on Health U.S. House of Representatives," June 21, 2007.

Smart v. Benecard
Documents Considered

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Appendix A

Smart v. Benecard
Healthcare Market Overview

1. In order to understand the complexities of the Medicare Part D Program, I have described in greater detail in this Appendix the structure around the Medicare Part D Program and the role of vendors. This Appendix is generally focused on the following areas:

   a. Medicare Part D program overview

   b. The Role of Medicare Part D Sponsors

   c. The Role of First Tier, Downstream, or Related Entities ("FDR"s)

Overview of Medicare Part D

2. The Voluntary Prescription Drug Benefit Program ("Part D") was established through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") as an amendment to Title XVIII of the Social Security Act. As of the program's effective date of January 1, 2006, Part D is an optional prescription drug benefit for individuals entitled to benefits under Medicare Part A or Part B. Part D coverage may be provided to beneficiaries in two ways: (1) under Prescription Drug Plans (PDPs) that strictly offer prescription drug coverage, or (2) through Medicare Advantage Prescription Drug Contracting (MA-PD) plans that offer prescription drug coverage integrated with the health care coverage they provide under Part C.[1]

3. Medicare Part D benefits are delivered via private insurers that contract with CMS to provide Medicare Part D plans. Part D benefits are funded in part by the program's

[1] CMS Medicare Part D Prescription Drug Benefits Manual (Medicare Part D PDBM), Chapter 1. Available at: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/partdmanuals.html.

participants and in part by Medicare. Medicare provides plans with a subsidy that averages 74.5% of the standard drug coverage costs. The monthly premium paid by the plan's enrollees covers the remaining 25.5% of the cost of standard drug coverage. The exact amount paid by Medicare to a specific plan is determined by the plan's expected costs of providing benefits as submitted to CMS in its annual bid.[2]

The Role of Medicare Part D Plan Sponsors

4. "Part D plan sponsors are nongovernmental entities that contract with CMS to offer prescription drug benefits through PDPs, MA-PDs, PACE plans, or cost plans offering qualified prescription drug coverage." In order to qualify as a Medicare Part D plan sponsor, a plan must meet all requirements under the regulation 42 CFR Part 423.[3]

5. A Part D sponsor must provide enrollees with qualified prescription drug coverage. Coverage may be may be provided in one of two ways: (1) directly by the Part D sponsor; or (2) through arrangements with other entities.[4] Part of the CMS contracting process requires the applicant plan sponsor to submit a bid defining their plan benefit package and a formulary defining the plan's covered products. "Medicare Part D Plans vary depending on

[2] 42 CFR § 423.329
[3] Office of Inspector General. "Memorandum Report: Medicare Part D Prescription Drug Plan Sponsor Internet Web Sites: Content and Accessibility."17 October 2007. Available at: http://oig.hhs.gov/oei/reports/oei-06-06-00340.pdf.
[4]Medicare Part D PDBM, Chapter 5 Section 20.1.

which pharmacies they use, which prescription drugs they cover, and how much they charge."[5]

6. The Plan Benefit Package (PBP) is a set of benefits for a defined service area. The PBP is submitted by PDPs and MA organizations to CMS for benefit analysis, marketing and beneficiary communication purposes. Plan sponsors can design their prescription drug benefit packages in a number of ways. One design tool commonly used is a formulary, which is the entire list of drugs covered by a Part D plan.[6] If a Part D sponsor chooses to use a formulary, it must meet CMS's requirements for an adequate formulary.[7] A Part D "covered drug" is defined as a drug that is dispensed only upon prescription and is used for a medically-accepted indication as defined by section 1927(k)(6) of the Social Security Act.[8]

7. Medicare Part D sponsors typically organize their formularies into tiers based on the cost of the drug. The tier a product is placed in most often determines the portion of the patient's cost sharing. Normally, cost sharing increases as the tier increases with the lowest cost drugs, often generics, residing in tier 1, and the most expensive drugs, often specialty products, residing in the highest tier. In specified circumstances, prescribers can ask for a lower copay for their patient when a drug from a higher tier is absolutely necessary for treatment.[9]

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[5] CMS. "How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules." October 2015. Available at: https://www.medicare.gov/Pubs/pdf/11136.pdf.
[6] Medicare Part D PDBM, Chapter 1.
[7] Medicare Part D PDBM, Chapter 5 Section 30.
[8] Medicare Part D PDBM, Chapter 6.
[9] CMS. "What drug plans cover." n.d. Available at: https://www.medicare.gov/part-d/coverage/part-d-coverage.html.

Smart v. Benecard
Healthcare Market Overview

8. Part D plan sponsors may employ utilization management (UM) programs at point of sale (POS), such as prior authorizations (PA), quantity limits (QLs), and step therapy (ST) when determining prescription drug coverage, as defined below:

a. Prior authorization (PA) requires the prescriber to receive pre-approval for prescribing a particular drug in order for that medication to qualify for coverage under the terms of the pharmacy benefit plan.[10]

b. Quantity Limits (QL) are limitations on the amount of the prescription product the plan will cover. Generally, the amount of drug is based on Food and Drug Administration (FDA) approved dosing and usage guidelines.[11]

c. Step Therapy (ST) protocol requires that a patient try and fail a less expensive, more established product before a more expensive prescribed product will be covered by the plan. If a patient has already tried the similar less expensive drug and was not responsive, a prescriber can call and ask for an exception.[12]

9. Plan sponsors are responsible for ensuring that products covered by the benefit are eligible for coverage under the Medicare Part D program and are prescribed for medically-accepted indications. Often this verification involves the use of UM measures. Plan sponsors

[10] Neil MacKinnon and Ritu Kumar. "Prior Authorization Programs: A Critical Review of the Literature." *Journal of Managed Care Pharmacy*, 7(4) (July/August 2001), 297.

[11] Johns Hopkins EHP. "Quantity Limits." n.d. Available at: https://www.ehp.org/plan-benefits/pharmacy/quantity-limits/.

[12] "How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules."

may also employ UM programs to ensure patient safety, reduce program costs, and provide a layer of fraud and abuse protection.[13]

The Role of First Tier, Downstream, or Related Entities (FDRs)

10. A Part D plan sponsor may meet program requirements by delegating the performance of certain required functions to entities with which it contracts directly, referred to in the Part D regulations (§423.501) as "first tier entities." These entities may in turn contract with other entities, defined as "downstream entities," for the performance of the delegated function. A "related entity" is an entity that is a parent, subsidiary, or subsidiary of the parent of the Part D Sponsor. A related entity may be either a first tier or downstream entity. [14]

11. Where a [Part D plan sponsor] applicant has elected to use subcontractors to meet Part D requirements, it must demonstrate that it has binding contracts in place that govern these relationships. These contracts serve as the legal links that form the applicant's "chain of delegation," extending from the applicant to the entities (first tier or downstream) that will actually perform the stated function on the applicant's behalf.[15]

12. Many FDRs are pharmacy benefit managers ("PBMs"). As a fundamental service, PBMs process prescription drug claims for plan sponsors and negotiate with pharmaceutical companies and pharmacies, essentially acting as an intermediary between the payers, suppliers and providers within the pharmacy benefit delivery continuum.

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[13] 42 CFR § 423.153(b).

[14] CMS. "2015 Capitated Financial Alignment Application." 2015, § 2.9. Available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/2015_MMPApplication.pdf.

[15] Ibid.

Smart v. Benecard
Healthcare Market Overview

13. In order to adjudicate prescription drug claims, a PBM must determine whether the prescribed product is covered. The PBM applies the plan sponsor's CMS approved formulary with its corresponding utilization management measures like prior authorizations (PA), step therapy (ST), and quantity limits (QLs) during the transaction to ensure appropriate coverage. CMS requires the use of utilization management, in part, to provide incentives to reduce costs when medically appropriate and to assist in preventing over-utilization and under-utilization of prescribed medications.[16] Plan sponsors also use utilization management measures to determine whether a certain prescription product should be covered under the Medicare Part D benefit.

14. Medicare Part D allows for certain beneficiary protections including a mechanism for beneficiaries to request consideration for coverage based upon their unique set of circumstances including a means to appeal an unfavorable coverage determination. To that end, Medicare requires that every plan sponsor establish and maintain processes for handling standard and expedited Coverage Determinations, Appeals and Grievances (CDAG).[17]

a. CMS defines a ***coverage determination*** as "any decision made by or on behalf of a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.[18]"

b. CMS defines an ***appeal*** as "any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan

[16] 42 CFR § 423.153(b).
[17] Medicare Part D PDBM Chapter 18, Section 10.2.
[18] Medicare Part D PDBM Chapter 18, Section 10.1.

sponsor on the benefits under a Part D plan that the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in §423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity (IRE), Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.[19]"

c. CMS defines a ***grievance*** as "any complaint or dispute, other than a coverage determination or an LEP determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested. A grievance may also include a complaint that a Part D plan sponsor refused to expedite a coverage determination or redetermination. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item.[20]"

15. As the benefit administrator, the PBM is often delegated, in whole or in part, CDAG administration functions.[21]

[19] Ibid
[20] Ibid
[21] Medicare Part D PDBM Chapter 18, Section 10.2.